



DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration  
Seattle District  
Pacific Region  
22201 23rd Drive SE  
Bothell, WA 98021-4421

Telephone: 425-486-8788  
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September 13, 2000

VIA FEDERAL EXPRESS

In reply refer to Warning Letter SEA 00-98

John T. Burke, M.D., Radiologist  
North Cascade Family Physicians  
2116 East Section Street  
Mt. Vernon, WA 98274

WARNING LETTER

RE: Inspection ID - 2117630005

Dear Dr. Burke:

We are writing to you because on August 22, 2000, your facility was inspected by a representative of the State of Washington, Bill Van Pelt, acting on behalf of the Food and Drug Administration (FDA). This inspection revealed a serious regulatory problem involving the mammography at your facility.

Under a United States Federal law, the Mammography Quality Standards Act of 1992, your facility must meet specific requirements for mammography. These requirements help protect the health of women by assuring that a facility can perform quality mammography. The inspection revealed the following Level 1 finding at your facility:

The system to communicate results is not adequate for North Cascade Family Physicians because:

1. There is no system in place to provide timely lay summaries;
2. There is no system in place to communicate serious or highly suggestive cases as soon as possible.

The specific problem noted above appeared on your MQSA Facility Inspection Report, which was issued to your facility at the close of the inspection. This problem was identified as Level 1 because it identifies a failure to meet a significant MQSA requirement.

Because this condition may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, it represents a serious violation of the law which may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to: placing your facility under a Directed Plan of Correction;

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charging your facility for the cost of on-site monitoring; assessing civil money penalties up to \$10,000 for each failure to substantially comply with, or each day of failure to substantially comply with, the Standards; suspension or revocation of your facility's FDA certificate; or obtaining a court injunction against further mammography.

In addition, your response should address the Level 2 findings that were listed on the inspection report provided to you at the close of the inspection. These Level 2 findings are:

1. 3 of 10 random reports reviewed did not contain an assessment category.
2. Corrective action for a failing image score (before further exams) was not documented for unit 2, [REDACTED] room Mammo.

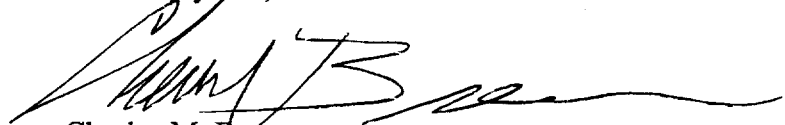
It is necessary for you to act on this matter immediately. Please explain to this office in writing within fifteen (15) working days from the date you received this letter:

- the specific steps you have taken to correct all of the violations noted in this letter;
- each step your facility is taking to prevent the recurrence of similar violations;
- equipment settings (including technique factors), raw test data, and calculated final results, where appropriate; and
- sample records that demonstrate proper record keeping procedures, if the findings relate to quality control or other records (Note: Patient names or identification should be deleted from any copies submitted).\*

Please submit your response to Thomas S. Piekarski, Compliance Officer, at the above mailing address.

Finally, you should understand that there are many FDA requirements pertaining to mammography. This letter pertains only to findings of your inspection and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for mammography facilities by contacting the Mammography Quality Assurance Program, Food and Drug Administration, P.O. Box 6057, Columbia, MD 21045-6057 (1-800-838-7715) or through the Internet at <http://www.fda.gov>.

Sincerely yours,



Charles M. Breen  
District Director

\*This note is not applicable for letters, which also address patient notification.

John T. Burke, M.D., Radiologist  
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Copy: Bill Van Pelt  
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Seattle, WA 98112

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